

# Computerized Clinical Decision-Support in Respiratory Care

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Computers were initially used in health care for billing and administrative functions. More recently computers have been used to present clinical information such as laboratory results and pharmacy orders. Many medical informatics researchers believe that the ultimate goal of the “electronic health record” should be to advance computerized clinical decision-support. This report considers the challenges of developing electronic-health-record systems and integrating them into useful computerized decision-support systems and presents a “pyramid of progress” concept that involves 5 steps: (1) to gather electronic health data into a standardized and coded format, (2) to validate the quality of that electronic health data, (3) to optimize presentation of electronic health data and explore computerized decision-support, (4) to develop and share computerized knowledge bases that are based on clinical evidence as well as consensus, and (5) to tailor and to implement the computerized strategies so that they fit into the workflow process of patient care. This report discusses 3 examples of successful computerized clinical decision-support (use of antibiotics, laboratory alerting, and ventilator management) and discusses strategies essential to making computerized clinical decision-support more widely available and useful. *Key words:* medical records, health records, computers, clinical decision support system, decision support techniques, evidence-based medicine, data collection, information management. [Respir Care 2004;49(4):378–386. © 2004 Daedalus Enterprises]

## Introduction

When most people think about using computers in medicine, they think of systems that help clinicians make di-

agnoses. In *Star Trek* episodes medical workers routinely pointed a device at an injured crew members and determined instantly what the problem was.<sup>1</sup> Because of the prevalence of such high expectations about the capabilities of devices and the general societal concerns about errors in

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medicine, there is a general belief that somehow, magically, computers will be able to take care of all of these concerns.<sup>2</sup> Unfortunately, that vision is far ahead of what can actually be accomplished even in the most advanced medical centers today. Musen et al defined a clinical decision-support system as, "any computer program designed to help health professionals make clinical decisions."<sup>1</sup> Thus any computer system that deals with clinical data and medical knowledge could be designed to provide clinical decision-support. For example, a well organized report of clinical data provided by the computer could be considered a clinical decision-support system.

The process of gathering clinical data and medical knowledge and putting them into a form that computers can manipulate to assist in clinical decision-support is still in its infancy. Computer performance has doubled about every 18 months for the past 30 years, and it appears that such doubling will continue for at least the next decade, but the development of the computer as an aid to clinical decision-making has not progressed nearly as quickly.

### Issues in Computerized Clinical Decision-Support

Early investigators of medicine-related computing, or "medical informatics" as it is known today, had hoped to be able to use the computer to gather clinical data from patients and to make diagnoses.<sup>3-6</sup> But as Blois so eloquently illustrated in his article in the *New England Journal of Medicine*,<sup>5</sup> and as Berner et al<sup>6</sup> recently discussed in that same journal, computerization of diagnosis is a complex and difficult problem. Therefore many investigators, including me, have taken a more pragmatic approach and have developed mechanisms to manually and automatically acquire important clinical data, which are then in a computer with the purpose of having the computer assist with clinical decision-making. The process of gathering clinical data is both challenging and rewarding. Today a major goal of most medical facilities, especially hospitals and large clinics, is to have a lifetime electronic health record. With such a record system we hope to gather the appropriate data and eventually use the acquired data to assist health care providers make better medical decisions.

### The HELP System at LDS Hospital

The following brief outline of the HELP (Health Evaluation through Logical Processes) system at LDS Hospital in Salt Lake City, Utah, will put the topic of computerized clinical decision-support systems in context. At LDS Hospital we have been developing and improving the HELP system for over 30 years.<sup>7-10</sup> Figure 1 describes the HELP system. Data are acquired from a wide variety of sources; some data are manually entered by nurses and respiratory therapists (RTs) at bedside computer terminals; some data

are automatically acquired from bedside monitoring equipment, using a system known as a *medical information bus*.<sup>11-13</sup> In addition, data from many other sources are collected and integrated into a structured medical database. The majority of the data elements are coded, meaning that the data set has a very specific and detailed structure. For example, inspired oxygen data are coded as to whether it is a flow rate (eg, 4 L/min) or a fraction of inspired oxygen ( $F_{IO_2} = 0.40$ ). Regardless of whether the data element was manually or automatically collected, each data element included (1) the time the data element was collected, (2) who collected it and if manually entered, and (3) the time the data were entered into the patient's record. With that coded and integrated structure the data can be used to assist medical decision-making. For example, an alert might be generated if a patient received 100% oxygen for more than 1 hour.

In Figure 1 the concentric circles surrounding the integrated clinical database indicate that as data are recorded into the database, "data-driven" decisions can be made. In addition, "time-driven" rules, such as the aforementioned example of 100% inspired oxygen for more than an hour, can be applied. The "knowledge base" block in Figure 1 represents the medical knowledge that is coded into the computer to assist decision-making. Using either data-driven or time-driven decision rules (knowledge), a sophisticated and powerful set of computerized strategies can be implemented. I will describe several examples of how the HELP system has improved patient care, to illustrate the challenges and power of computerized clinical decision-support.

In the process of developing, testing, evaluating, and maintaining the HELP system over several decades, we at LDS Hospital came to realize the complexity and challenges of implementing sophisticated computerized decision-support systems. We developed a "pyramid of progress" diagram (Fig. 2) that summarizes the sequence and the primary issues and challenges in developing a computerized decision-support system.

### Acquiring the Data

A fundamental part of any computerized clinical decision-support system, just as with any human clinical decision system, is the acquisition of data. The expert clinician develops both interpersonal and technical skills to collect accurate patient data during physical examination and history-taking, and making a correct diagnosis and treatment decision depends on the quality of the clinician's observations and inferences; that is, fundamental measurements are crucial to providing quality patient care. Likewise a computerized clinical decision-support system depends on quality data.

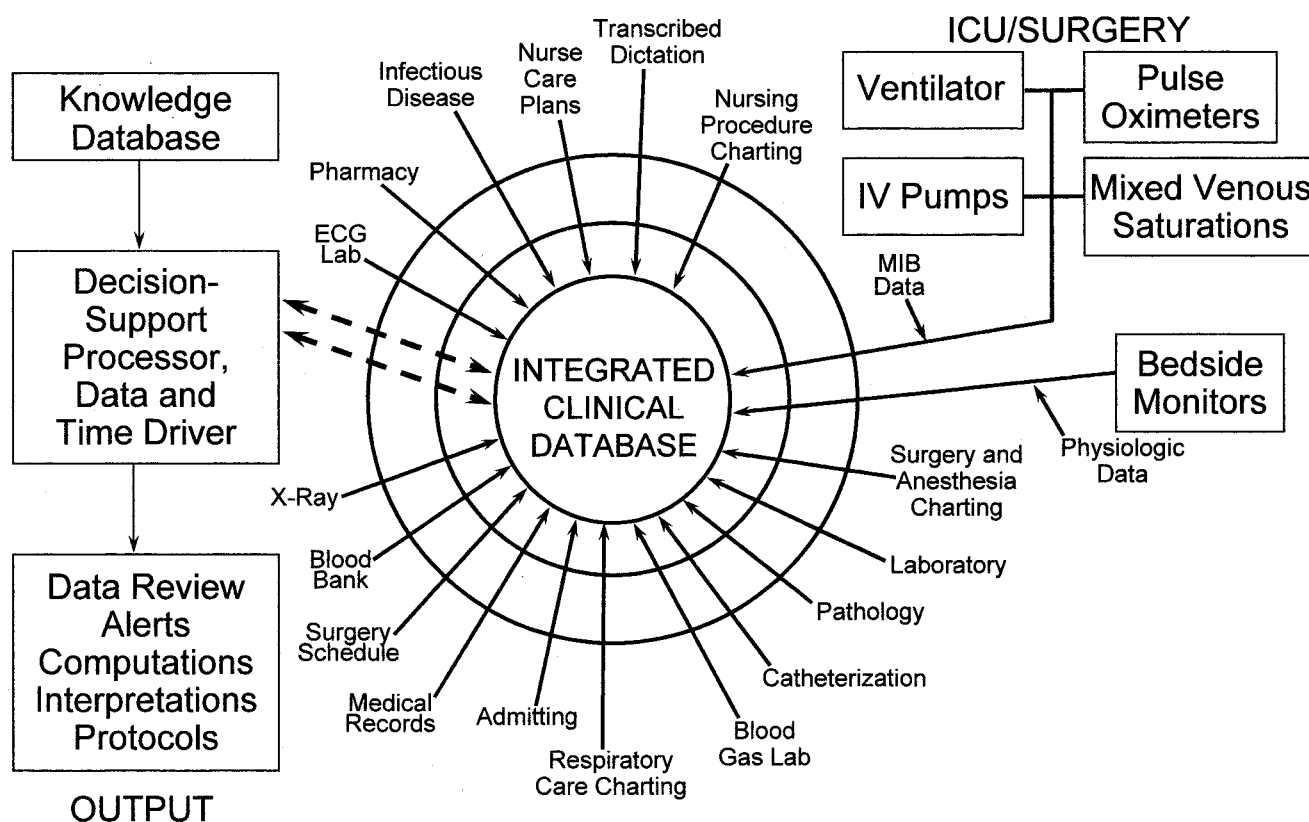


Fig. 1. The HELP (Health Evaluation through Logical Processes) computerized clinical decision-support system developed at LDS Hospital in Salt Lake City, Utah. ICU = intensive care unit. IV = intravenous. ECG lab = electrocardiography laboratory. MIB = medical information bus (see text).

Most medical data are still collected on paper flow sheets. Although these flow sheets are comfortable for most clinicians, the data thus acquired are typically unavailable for computerized clinical decision-support. Further, even though many patient data come from computerized devices such as monitors and ventilators, those data are manually logged onto flow sheets. Other medical information, such as progress notes and instructions for care are also handwritten, further slowing the progress toward computerization and computerized clinical decision-support. Some chart notes are dictated and transcribed into a computer record and become word-processing documents, which are easier to read than hand-written notes, but such notes are in a "free text" format that is difficult for a computer to understand and process. Recently, voice-recognition dictation systems and "natural language processing" methods have shown some promise for recording data directly into a computerized format.<sup>14</sup> Unfortunately, the technologies needed to change "free text" into computer-interpretable, coded data are fraught with complex issues of interpretation; so if we are to make progress toward computerized clinical decision-support, we will have to work at getting health records stored as coded, structured data.

Deciding what code to use is also problematic. Until very recently developers and manufacturers of electronic medical record systems have typically used uncoded data or used their own ad hoc coding scheme. In 1986 the National Library of Medicine began a long-term project to build and refine a Unified Medical Language System,<sup>15</sup> the purpose of which is to make it easy for users to link information from disparate computer systems, including electronic health records systems. With the Unified Medical Language System it is now possible to accurately and efficiently link several systems. In July 2003 the National Library of Medicine took an additional leadership step by purchasing the Systematized Nomenclature of Medicine Clinical Terms from the College of American Pathologists. The Systematized Nomenclature of Medicine Clinical Terms is now being incorporated into the Unified Medical Language System, so anyone in the United States now has free public access to the world's most comprehensive computerized medical terminology system.<sup>16</sup>

Data entered into an electronic health record answer the questions *who*, *where*, *when*, and *how*. This is a complex issue, as will be illustrated in some examples below. There are 2 basic methods for data entry: (1) automatic entry

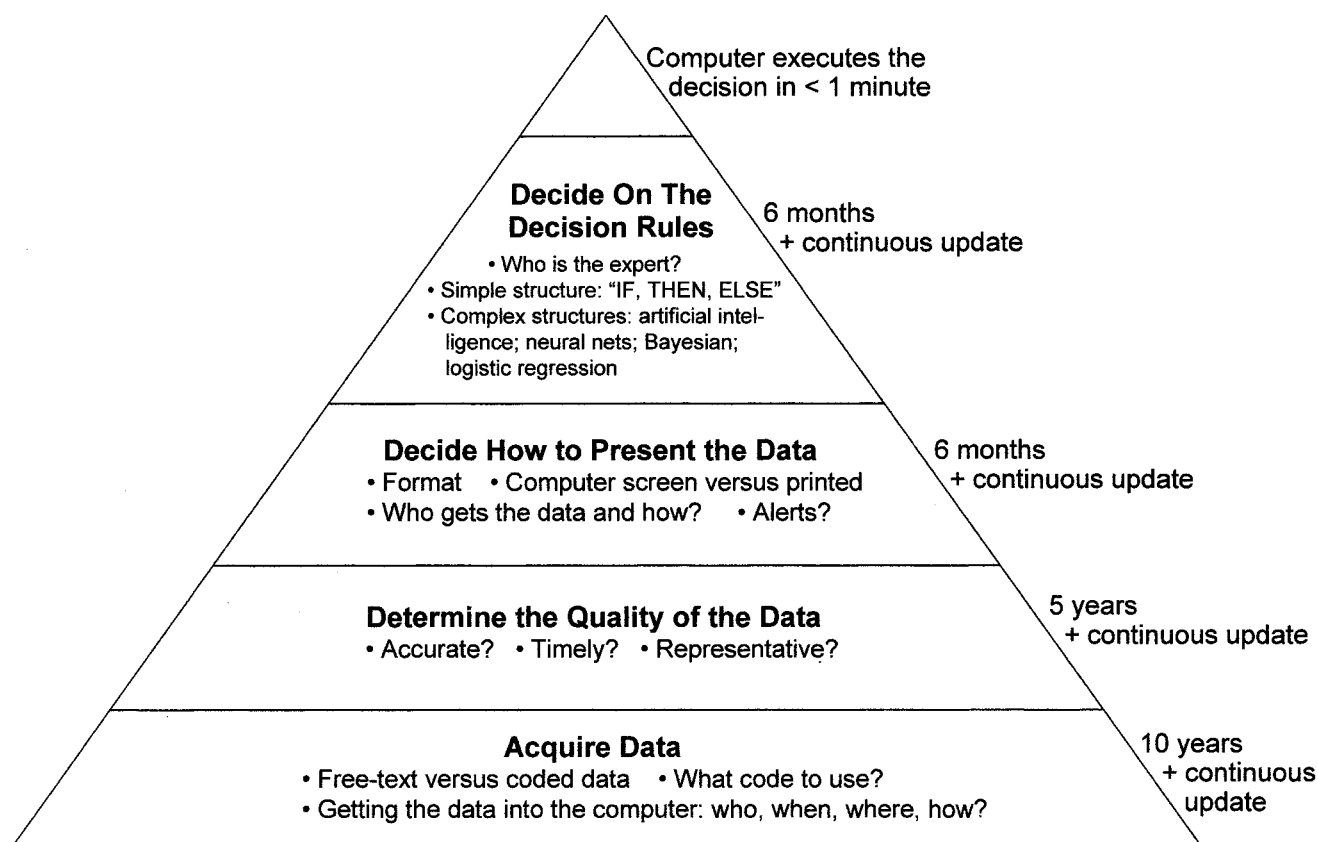


Fig. 2. The "pyramid of progress" outlines the steps in developing and implementing a computerized clinical decision-support system (see text).

from electronic instruments at the bedside and (2) manual entry, using a keyboard, touch screen, voice input, or other input system. For electronic health records to be of most value they must be entered during the patient visit. Unfortunately, conventional, manual, on-paper charting schemes seldom promote immediate charting, but instead allow for or even encourage delayed or end-of-shift charting, much like one might write in a daily diary. Such delayed charting can cause major problems, related to the expectations of the users of electronic health records, who are not necessarily on site but might be in the operating room, at another nursing division, in the cafeteria, in an office, or even at home. For computerized clinical decision-support to be effective the data in the computer must be up to date. For example, if you are attempting to wean a patient from a ventilator and 2 hours ago you decreased the fraction of inspired oxygen ( $F_{IO_2}$ ) from 50% to 40%, but you haven't electronically charted that  $F_{IO_2}$  decrease, any computer-aided decision will be based on the (incorrect) 50%  $F_{IO_2}$  until you enter the new  $F_{IO_2}$  value. Even if the strategy and decision rule set for decreasing the  $F_{IO_2}$  are perfect, the incorrect data in the computer could cause a treatment error.

The entire process of developing and implementing a system for acquiring data that can be used for computerized clinical decision-support is complex, so gathering some data elements has taken a decade or more. Although computing technology and capabilities have improved dramatically, the fundamental problems of computerized medical coding systems and data gathering have only recently begun to be comprehensively addressed. Consequently, developers and adopters of such systems should plan for and be prepared for changes and challenges in the process of implementing such systems and should *not* hold unrealistic expectations that such systems can just be turned on and immediately manage data exactly as desired.

### Data Quality

Figure 3 illustrates some of the data-quality issues in computerized health record systems. The top panel of Figure 3 shows that the  $F_{IO_2}$  data recorded by the RT was a constant 40%. However, the continuous data recorded from the medical information bus shows that the  $F_{IO_2}$  was increased to 55% at about 60 min, was returned to 40% at 240 min, and at 500 min the  $F_{IO_2}$  was increased to 100%

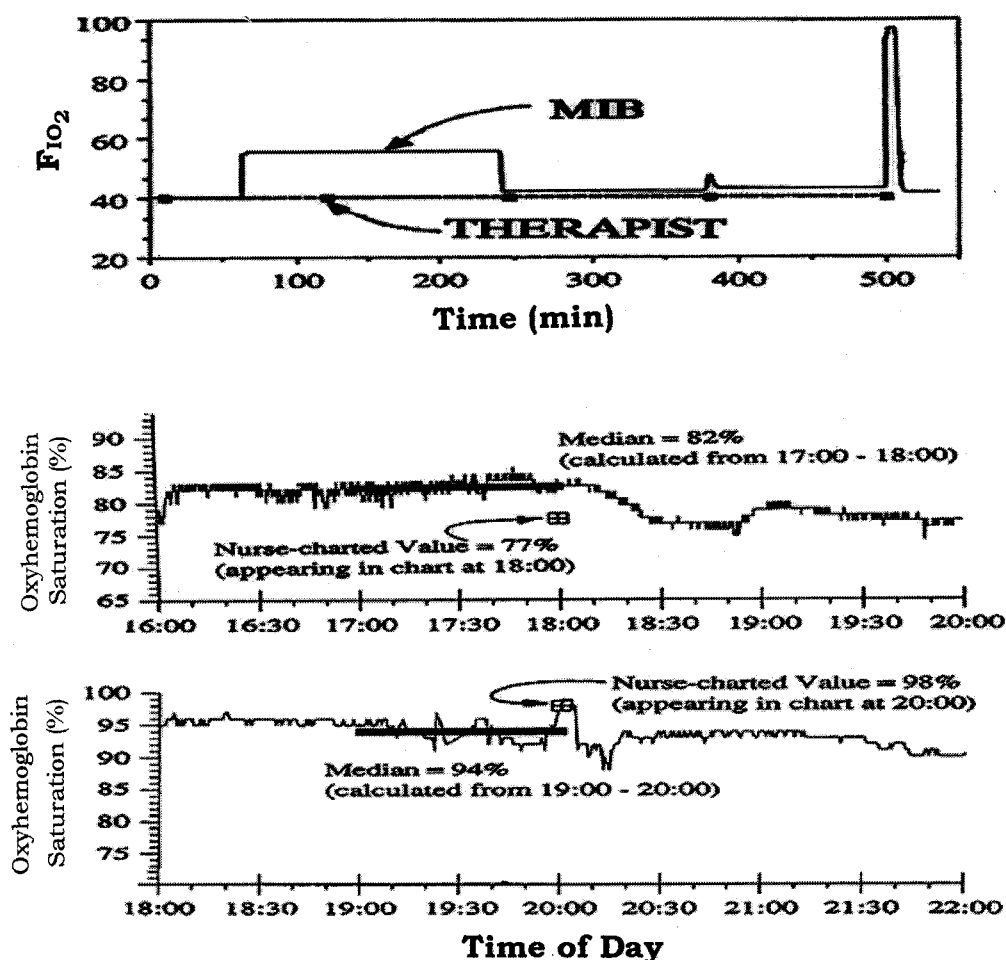


Fig. 3. Medical information bus (MIB, see text) data versus data recorded by clinicians, from 3 different intensive care patients. Top panel: Fraction of inspired oxygen ( $F_{IO_2}$ ) readings recorded by the MIB (from the ventilator) versus the  $F_{IO_2}$  recorded by the respiratory therapist about every 2 hours. The respiratory therapist failed to record several periods in which  $F_{IO_2}$  had been temporarily changed. Middle panel: Continuous oxyhemoglobin saturation values recorded by the MIB, versus by a nurse at 18:00. The nurse recorded a saturation of 78%, but the median value between 17:00 and 18:00 was 82%. Lower panel: Oxyhemoglobin saturation values recorded by the MIB, versus by a nurse at 20:00. The nurse recorded a saturation of 98%, but the median value between 19:00 and 20:00 was 94%.

for a short interval. That discrepancy between the RT-recorded data and the machine-recorded data illustrate one type of data accuracy problem.

The middle panel of Figure 3 shows that a nurse recorded an oxyhemoglobin saturation of 77% at 18:00. However, at 18:00 the medical information bus recorded that saturation was really 82%. What probably happened was that the nurse had orders to record the saturation every 2 hours but didn't get to the patient's bedside until about 18:30 and recorded the saturation at 18:30 (78%) but wrote it down as being the value at 18:00. This example illustrates a timing accuracy problem.

The bottom panel of Figure 3 illustrates a data-selection recording problem. The nurse recorded a 98% saturation, whereas the continuous medical information bus data showed that the patient only had a 98% saturation for a

few minutes at about 20:00 (the mean saturation between 19:00 and 20:00 was 94%).

With manually-recorded systems these data-quality issues are not as obvious as they are with electronic health records. Since electronic health records are the basis for computerized clinical decision-support, these data-quality issues must be dealt with. Other experimental work at my institution, including data on intravenous pump drip rates, showed similar issues with data accuracy, representativeness, timing, and timeliness of charting.

Gathering computerized data can take time and careful planning. In most cases, when transitioning from a manual, on-paper system to a computerized system, the processes for gathering and recording data must be dramatically changed. We estimate that it will take upwards of 5 years to gather complete and accurate electronic health



records. Furthermore, the quality process will need to be updated continuously in order to facilitate the acquisition of new data and the advancement of new therapies.

### Presenting the Data

Once data have been collected, their quality verified, and the results stored, then you must decide how the data will be presented. One of the first decisions is whether to present the data via computer screen or to print them. It is necessary, of course, to store patient data electronically so they can be manipulated and used for computerized decision-support, but many people assume that an electronic health record system must be entirely paperless. The question of whether to display data on a computer screen or on paper is still unresolved. Paper has some marvelous characteristics. You can carry it with you. Once data are printed, they can be reviewed without the need of an electronic device. The number of characters and graphics that can be displayed on a sheet of paper still exceeds what can be displayed on most monitors. Paper can be folded and put in your pocket and you can use it to take notes. So, at present, printed data still has advantages in some situations.

How to format the data presentation is another important consideration. Should the data be presented in numerical or graphical form? How do you decide? Clearly, the interface between people and data is still being developed and data display methods will continue to evolve.

There are also issues regarding how to communicate data. If laboratory findings indicate a life-threatening condition, who should be notified and how should the results be transmitted? Fortunately, computer communications are becoming increasingly wireless, so important results can be immediately, easily, and reliably sent to the appropriate people. However, determining who should get such results requires building an infrastructure that is not currently in place in most health care organizations. Since a patient's assigned caregiver changes at the end of a work shift, the computer must track who is responsible for which patients at what times; whenever a new medical consultant cares for a patient, the computer system must be aware of that change. Many centers do not yet have the systems and policies necessary to rigorously track such information.<sup>17,18</sup>

### Deciding on the Decision Rules

Deciding on what decision rules are to be installed in a computerized clinical decision-support system is difficult. Health care is currently being driven by the objective of implementing evidence-based medicine, care protocols, and clinical practice guidelines, which have been developed for many branches of medicine. However, so far few guidelines have been implemented by way of computers.<sup>19,20</sup>

One of the best ways of deciding on the treatment-decision rules is to develop a consensus process, by gathering your institution's experts together and agreeing on methods to search the literature, integrate their clinical experience, and determine the rules for your institution. It would be ideal if the consensus group's treatment-decision rules were widely agreed to and adopted by those who were not in the consensus group, but differences of opinion and different local practice needs should be expected. For example, seldom are national guidelines and protocols accepted without local modification. In many cases such modification is essential because of factors such as altitude. Salt Lake City is at 1,500 meters altitude, so modifications to some decision rules and protocols are essential.

Although many clinicians think they are *the* experts, it is seldom that the decision rules such persons develop are widely accepted and used. However, in some departments there may be a trusted clinical leader who can become the agreed local expert.

Still another issue that must be considered is what type of decision rule set should be developed. The simplest form of rule set uses the branching-logic "IF, THEN, ELSE" structure. For example, IF a person's body weight is 200 kg, THEN the person is overweight. Another example is, IF a 183 cm tall, 40-year-old male patient has a forced vital capacity of 3.5 L (predicted value 5.43 L), THEN the patient has severe forced vital capacity restriction.<sup>21</sup>

For many situations more sophisticated and complex decision-support strategies may be applied. Such rule sets fall into the categories of artificial intelligence, neural nets, logistic regression, and Bayesian networks.<sup>22</sup> In medical informatics these methods have become important for handling situations where uncertainties and probabilities are involved.

Developing the rules for clinical decision-support is complex, and the rule set is always subject to revision. Developing the rules can take up to 6 months and the rule set will need continuous review and updating. Furthermore, it is important that once decision-support rules and protocols are developed, they be easily shared among institutions. There have been 2 recent developments to enhance sharing of computerized decision-support strategies. The first is Arden Syntax, which was developed by an international collaborative group during the 1990s.<sup>23</sup> More recently, Guideline Interchange Format was developed to allow exchange of clinical practice guidelines.<sup>24</sup>

### Executing the Decision

Once the challenges at the base of the pyramid of progress have been addressed, the computer can usually make its calculations and render clinical advice within seconds. The major problems in developing a computerized clinical de-

cision-support system are in the base of the pyramid of progress.

### Three Successful Uses of Computerized Clinical Decision-Support

Based on our experience at LDS Hospital and the experience of other institutions with similar systems, I will discuss 3 successful uses of computerized clinical decision-support: (1) antibiotic use and infection control, (2) alerting clinicians to important new laboratory values, and (3) ventilator management.

#### Antibiotic Use and Infection Control

Based on several decades of research, computerized decision-support at LDS Hospital has improved the detection and control of nosocomial infections and the use of antibiotics. Scott Evans has been the chief medical informatics scientist for most of the work. The initial research was on using coded microbiology results to optimize antibiotic use.<sup>25</sup> It was determined that prophylactic antibiotics were not being given consistently before complex surgeries such as open heart surgery and total hip replacement. Although it seemed apparent that prophylactic antibiotics should be given before the surgery, it was not known exactly when was the best time to give the antibiotics. Using data from a computerized surgical schedule and computerized infection data, Classon and colleagues determined that the optimum time to give such prophylactic antibiotics was during the 2 hours just before the surgery.<sup>26,27</sup> Based on that research, published in the *New England Journal of Medicine*, a small addition was made to the computerized operating room schedule so that the staff would be alerted that a prophylactic antibiotic should be administered before the surgery. Clinician compliance improved after implementing that computer-assisted process.

In a study to assess the costs of, and to seek ways to prevent, adverse hospitalization events such as nosocomial infections, Classen et al<sup>28,29</sup> reviewed computerized patient records. Using a case-control methodology, patients who had nosocomial infections were compared (matched by gender, age, type of surgery, and other variables) with those who did not suffer nosocomial infection. Among patients who suffered nosocomial infection, mortality was about 6 times higher, length of stay was > 5 days longer, and hospital costs were about \$5,000 higher. Thus it became abundantly clear that preventing nosocomial infections was crucial.<sup>28,29</sup> Computer-assisted antibiotic practice guidelines decreased overall antibiotics use by 22% and decreased infection-caused mortality from 3.65% down to 2.65%.<sup>30</sup> In addition, adverse drug events (many of which are caused

by antibiotics) were reduced by 30% and the per-patient cost of antibiotics was reduced by > 40%.<sup>30</sup>

Based on those successful implementations Evans et al began work on a computerized "antibiotic assistant" ordering methodology.<sup>31</sup> When a physician chooses to order antibiotics, the system—using the patient's data (previously stored in his electronic health record)—presents important information about the patient's allergies, renal function, microbiology results, and sensitivities. Based on that information and the unit in which the patient is located (which the computer also knows), the computer suggests the best and least expensive antibiotic and its dose, route, and interval. The system has been very successful. The entire process of gathering the data from the computer record takes < 4 seconds, versus 14 min if gathered by a person. Incidents of antibiotic allergy reaction were decreased by half, adverse drug events were decreased by almost 4-fold, excessive antibiotic dose events were halved, mismatches from microbiology laboratory susceptibility tests were decreased by almost 10-fold, and excessive time on antibiotics was dramatically decreased.<sup>31</sup> In short, computer-assisted decision-support dramatically improved antibiotic use at LDS Hospital.

#### Laboratory Alerting

The reporting of critical values from the laboratory to clinicians is an important function. The success of critical-values reporting depends on laboratory personnel recognizing the critical values and effectively communicating them to clinicians. Further, the clinicians receiving the alerts must properly interpret the critical values and provide appropriate care.<sup>15,16</sup> Unfortunately, investigators have shown that (1) not all critical values are reported, (2) when critical values are reported, they are usually not reported to the primary clinician caring for the patient, and (3) reporting documentation tends to be incomplete from both the laboratory and the clinician.

Karen Tate and her associates at LDS Hospital developed and evaluated 2 computerized critical-values reporting systems.<sup>17,32,33</sup> The first attempt at reporting critical values used simple on-screen displays, which were found ineffective. Subsequently, they tried a flashing yellow light, similar to those used on snow plows. The flashing yellow light was effective, causing clinicians to promptly review the critical values and take appropriate action, but the light was too obtrusive in the clinical environment. A subsequent implementation of the critical-values reporting system paged the assigned nurse. This electronic paging system was much more effective and direct and resulted in more complete alert follow-up and care.

Kuperman et al developed a critical-values reporting system at Brigham and Women's Hospital in Boston.<sup>18</sup> That system tracks which clinicians (usually house staff physicians) are assigned to care for particular patients and the clinicians are promptly notified via the hospital's paging system. The computer presents the responsible physician with "order sets" for each of the alert conditions. Critical values are detected and reported faster, and a randomized, controlled trial showed that the time-to-treat and time-in-alerting-condition were reduced. Kuperman et al concluded that an automated alerting system can reduce the time between the treatment order and its delivery.

### Ventilator Management

Developing a robust and practical computerized clinical protocol is time-consuming.<sup>20,21</sup> Computerized protocols for managing ventilator care and weaning patients from ventilators are becoming more widely used.<sup>34–37</sup> The complexity of care and potential for information overload have led to development of better treatment algorithms. There are still many challenges, but there have also been many successful developments and sharing of these computerized protocols.<sup>19,20,34–37</sup>

### Summary

So what has changed with computerized clinical decision-support in the past 20 years? Clearly, there have been marvelous and outstanding changes in computer hardware. Computers are smaller, faster, easier to use, more reliable, and much less expensive—costing < 5% of what the same computing power cost 20 years ago. Computer networks have become ubiquitous, including wireless networks that are now mature and standardized. We now have the Internet and the Web easily available to almost everyone. Several National Health Information Infrastructure standards now exist and more are being developed. The United States National Library of Medicine has begun establishing additional vocabulary standards. Those steps will facilitate development of electronic health information systems and make that information easier to share.

The problems and issues that must be resolved to climb the pyramid of progress now seem to be understood and solvable, but solutions won't come easily or quickly and sharing and collaboration will be crucial. We are starting to understand the cognitive issues that must be dealt with in computerized decision-support.<sup>38</sup> The opportunities are great and promising. Investigators should vigorously pursue computerized clinical decision-support and try new techniques and strategies. And, as Tierney and McDonald stated so well in 1996, there is tremendous value in reporting "negative" results from informatics experiments.<sup>39</sup>

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## Discussion

**MacIntyre:** I guess I'm rehashing previous comments, but it still continues to amaze me that we have been so slow to develop computerized clinical decision-support tools for antibiotics. Those systems can reduce drug reactions and improve outcomes and they do not *demand* that you use a certain antibiotic regimen; it's a suggestion system based on a very straightforward set of rules. Why are we so slow to bring those systems on line?

**Gardner:** We use one at LDS Hospital and Intermountain Health Care, which is a consortium of 22 hospitals, and it's used at 9 other hospitals besides LDS. The main reason such systems have not been implemented elsewhere is that the data aren't there at those other smaller hospitals and rural communities; they haven't got sufficient data to do the decision-making process.

**MacIntyre:** Do you think that's a limitation of application, the input of data, or do you think it's a cultural thing, meaning that doctors just don't

want to give up the opportunity to screw around with antibiotics?

**Gardner:** Oh, the doctors can still screw around with antibiotics. The compliance with the "antibiotic assistant" is a little over 50%. But once they choose a medication, if they decide to choose something other than that, the dose, route, and interval compliance is in the 90% range.

**MacIntyre:** It still just amazes me! It seems like a no-brainer that that kind of stuff should be more used now, 5 years after your *New England Journal* article was published.<sup>1</sup>

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**Gardner:** I asked Dr Marc Overhage at the Regenstrief Institute (where Dr Clement McDonald and that group are) why it isn't used there, and I also asked Dr Gil Kuperman why it isn't

used at Brigham and Women's, and they said they couldn't get consensus. So they're up near the top of the pyramid of progress [see Fig. 2].

**MacIntyre:** That's the same thing I get at Duke. I bring this up, talk to individuals, and they say "that's really a good idea," but getting the institution as a whole to devote the resources to develop it and get it done—it seems to run out of steam somewhere.

**Ward:** I come from a hospital that's pretty well computerized but not completely; we have lots of gaps, and that's one of them. I think there are 2 hurdles that have to be overcome to implement a system like that. One is a big-hospital problem and the other is a small-hospital problem.

The big-hospital problem is that it's expensive; you've got to convince people that the system will save money. That seems to be our hurdle. But I think probably the more common hurdle, out there in the rest of the world, is that this system needs to be part of a larger system; there needs to be some sort of computer system that the physicians and nurses and RTs go to reg

ularly every day that the antibiotics information also comes up on. If they're still charting on paper, and reading laboratory results from paper, and they aren't regularly having to go to a computer as part of their job, they're not going to make a special trip over to a computer to see if there's any antibiotic warnings. There are still a lot of intensive care units out there that are relatively uncomputerized. So they have to install this as part of a more comprehensive computer system.

**Gardner:** One of the huge issues is economics. Who's going to pay for it? There is also the infrastructure problem: the infrastructure still isn't there. We should have standard data sets so that we use a common vocabulary to share data, no matter which company built the system. When our hospital bought a system, the primary consideration was whether the company would be in business 5 years from now when we bring the system online. And that's a sad commentary.

**Nelson:** Canada has a wonderful national health care system, in which everything is structured: clinicians have a limited set of things they're allowed to do and they have strict procedures that they have to follow: they can't just run off and do anything they want, like United States physicians are accustomed to. Would it be good for the United States to adopt a national health system that would require developing standard procedures, so that all patients are treated the same way for a given condition, whether they're in La Jolla, California, or Bangor, Maine?

**Gardner:** The theory is great, but a national health system has substantial political and infrastructure issues. The Canadians considered issuing health cards to everybody, and they did an experiment, I think it was in Québec, to see how health cards would work. But they are even more zealous than we are about the privacy of their health

information, and the health card idea failed because people were afraid they were going to lose privacy and that someone would read their health records. I think the card was a really good idea, but that's an example of how not all good ideas work.

**Stewart:** I think we're starting to head in the direction Steve Nelson mentioned with regard to standards and protocols. The Charleston Area Medical Center [Charleston, West Virginia] has a demonstration project underway related to clinical outcomes with pneumonia, coronary bypass surgery, congestive heart failure, and acute myocardial infarction, and tied to that are the outcome standards. For example, the use of  $\beta$  blockers for congestive heart failure patients, the timeliness of antibiotic delivery for pneumonia patients, the type of antibiotic delivery, and the use of flu and pneumonia vaccines in those populations all have dollars tied to them now. This will increase the health care delivery system's reimbursement based on how well they perform to those standards. It's going to be interesting to see what that demonstration project finds.

**Gardner:** Intermountain Health Care is now marketing the fact that they have a nearly lifetime electronic medical record, so if you've been in one of their hospitals and you happen to go into an emergency department in southern Utah, they have access to your medical records. They are now marketing that, with one of their pediatric intensivists talking about it on TV, and I've seen it enough times I have it memorized.

**Volsko:** Regarding the "smart card"—the health cards the Canadians tried—you're right, they did have strong security/privacy concerns. They used encryption codes and they compartmentalized the cards so that there were different levels of security, and the end users (I think there were over 200 health care practitioners who were

smart card users) had security access codes and the code determined what level of information they were allowed to access.

But some of the problems they experienced were similar to what we experience with paper charting, or with some of the systems we have in place that aren't as technologically savvy: they had patients who forgot their cards, so they weren't able to document a clinic visit, or family members didn't bring the card in for hospitalized patients, so they had difficulty catching up on the information that way. They also had problems with the users not being comfortable with the technology—a noncompliance issue. A health information system has to be in a format that's easy to use and that people are *willing* to use.

**Gardner:** And to their credit, they published their negative findings and that's absolutely crucial. A researcher I once worked with said, "You only publish the top 1% of what you do." but I hope we never do that. I hope we publish our failures, because we may learn more from our failures than from our successes.

**Ford:** I've talked with manufacturers of RCMISs [respiratory care management information systems] and clinical information systems, and they expressed concerns about developing decision-support software. Does the incorporation of decision-support functions in an RCMIS result in it being considered a medical device by the Food and Drug Administration and thus make it subject to regulation? Is that a valid concern, and if so, how can we help them work through it?

**Gardner:** The software oversight committee concept was developed by the American Medical Informatics Association and we tested the idea. It turns out that if you give the clinicians the rule set, and the engine that runs the rule set, the clinicians then

maintain the responsibility. And, to my knowledge, at this point the only thing the FDA has regulated in hospitals is blood-banking systems. They did that because in some cases they had files open and things changed and some people got wrong blood. But the FDA has been quite open about it, and I think will be very responsive to the software oversight committee concept. At our place we have attorneys, risk management, hospital administration, physicians, nurses, RTs, everyone. The issues are very interesting and, even though we've been at it for 20 years, we still know where our warts are.

**Hopper:** I want to comment about the frustration Dr MacIntyre expressed. It's not confined just to this

subject, as I'm sure you know. I think you're right on target by pointing out that it's not a technical problem for an innovation to spread; it's a social challenge, and that frustrates a lot of people with really good technical innovations. But there is a whole body of research and theory out there on diffusion of innovations and on change management. This would be the next step, as distasteful as it is to technical people, and that's what it would take to get something this complex to be widely accepted.

**Gardner:** I agree with you. The National Health Information Infrastructure is something that Ed Hammond, the president of the American Medical Informatics Association, has been

pushing. See the Institute of Medicine's report called "Key Capabilities of an Electronic Health Record System"<sup>1</sup> that discusses understanding the hospital's readiness for computerized physician order entry. There's information becoming more and more available to a broader group, and you know we're pioneers because pioneers have arrows in their backs, and we've got lots of them.

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